OUTCOMES FROM RAYONE HYDROPHOBIC IMPLANTS IN FRANCE

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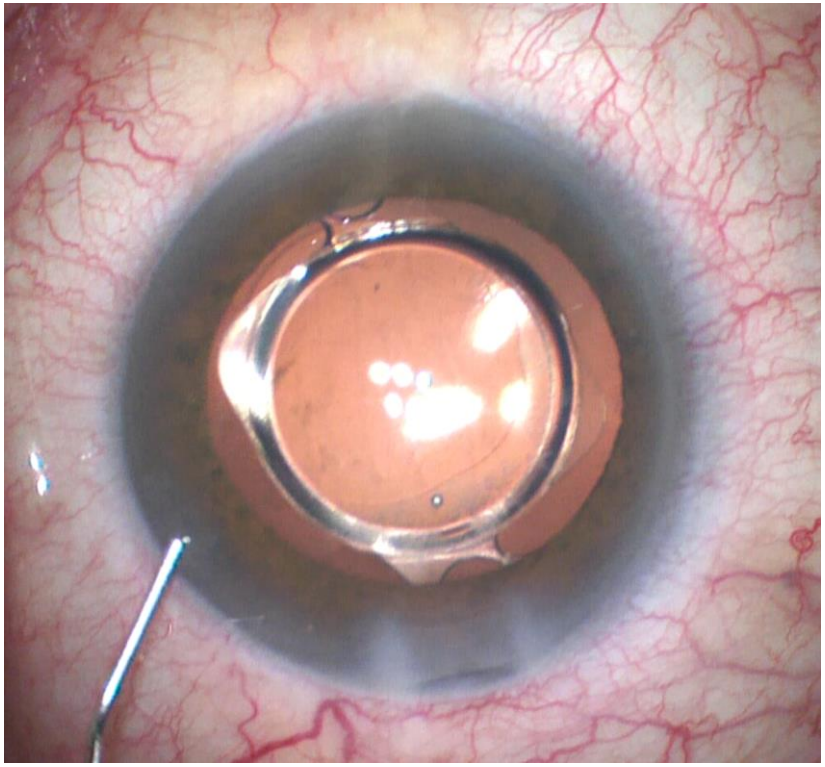
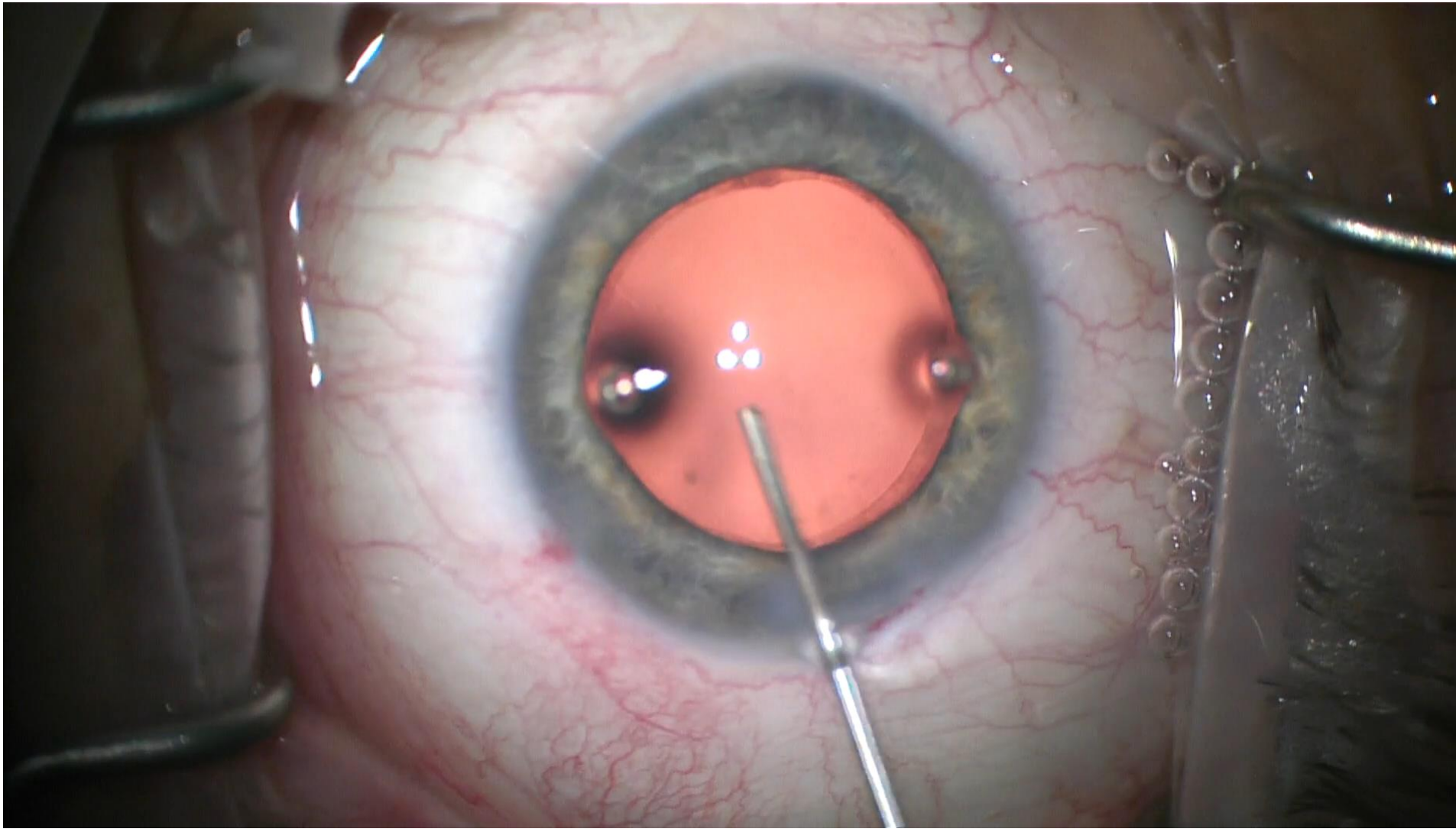
WHAT ARE THE CURRENT REQUIREMENTS FOR INTRAOCULAR LENSES?

REQUIREMENTS FOR IOLs

- Biomaterial properties:
  - No PCO
  - Fast bioadhesivity to posterior capsule
  - Glistening-free
  - Rotational stability within the bag (Toricity)
  - Foldable (small incisions)
  - Preloaded
- Optical properties:
  - Aspherical
  - Wide range of IOL power
  - Reproducibility of visual and refractive results



SURGERY- IOL IMPLANTATION



MATERIALS & METHODS

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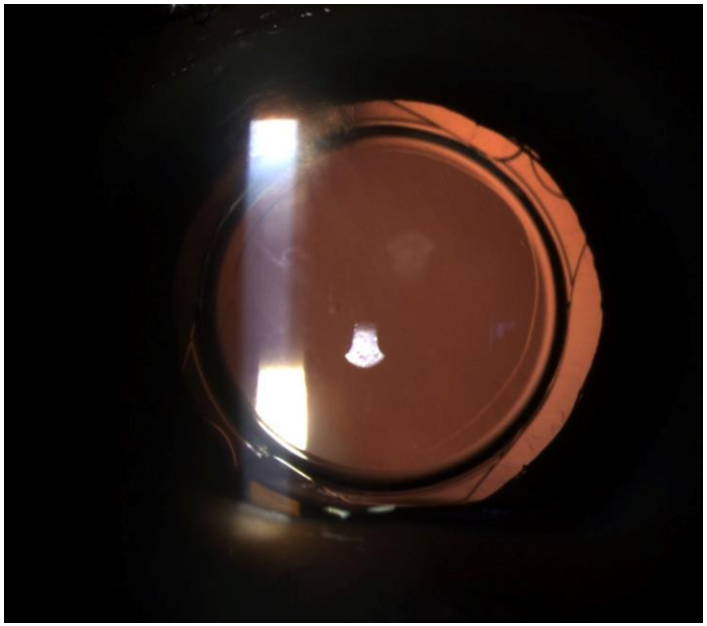
- Prospective pilot study
- August 2018-September 2018
- Setting: Bordeaux University Hospital (France)
- Participants: Consecutive patients complaining for decrease in VA or visual disturbances related to opacification of the crystalline lens
- 2 surgeons
- Procedures:
  - Standard of care cataract surgery using PKE and implantation of a foldable Hydrophobic acrylic IOL in the capsular bag
  - Follow-up Day 3 and Month 1
- Exclusion criteria:
  - Inability to give written consent

MATERIALS & METHODS

- Surgical procedure recorded
- **Visits**: Day 0, Day 3, Month 1
- **Outcomes:**
  - Day 0 visit:
    - Total Surgical time and Unfolding time
    - Intraoperative complications
  - Month 1 visit:
    - VA and absolute refractive error
    - Glistening, PCO
    - IOL rotational stability using slit lamp photography (D3-M1)
    - IOL Tilt and centration using Swept-source anterior segment OCT (Casia, Tomey) Optical aberrations using Ray tracing (Itrace, USA)



RESULTS

DEMOGRAPHIC & OPHTHALMOLOGICAL CHARACTERISTICS

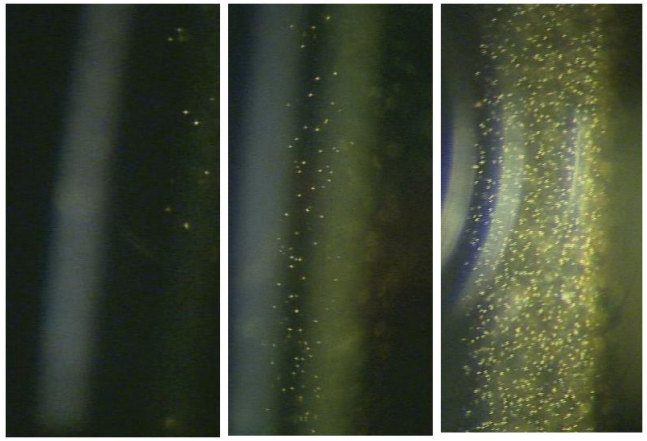
Characteristics	RayOne population (n=11)
Mean age at surgery (years) (SD)	73,1+/-11,8
Gender-female subjects (%)	45,5
Number of right eyes (%)	45,5
Mean preoperative UCVA (LogMAR)	0,31+/-0,43
Mean preoperative BCVA (LogMAR)	0,15+/-0,17
Mean preoperative absolute refractive error (Diopters) (SD) (min-max)	1,53 +/- 2,57 (0-8,5)
Mean IOL Power implanted (Diopters) (SD)	20,4+/-2,3

INTRAOPERATIVE RESULTS

Intraoperative characteristics	RayOne population (n=11)
Total intraoperative surgical time (Seconds) (SD)	448,3+/-143,0
IOL positioning and unfolding time (Seconds) (SD)	25,4+/-10,7
Inappropriate IOL folding within the injector	0
Intraoperative complications	0

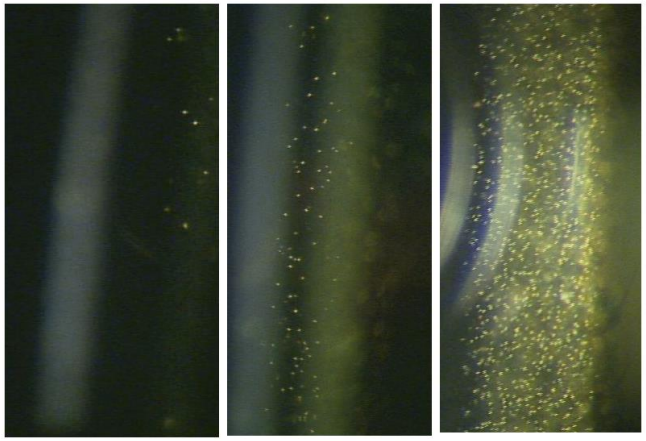
ANATOMICAL OUTCOMES

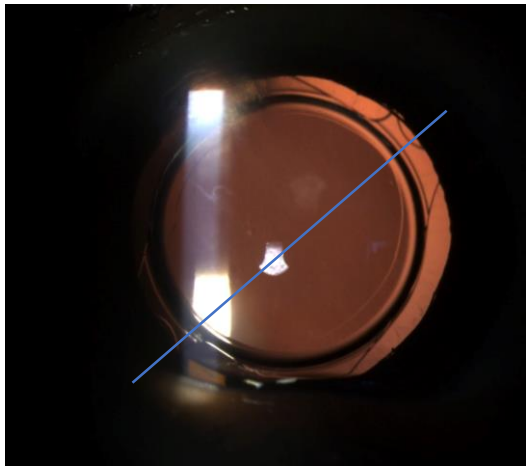
Characteristics		RayOne population (n=11)
Glistening (%)	<50 microvacuoles/mm2	100%
	50-150 microvacuoles/mm2	0%
	>150 microvacuoles/mm2	0%



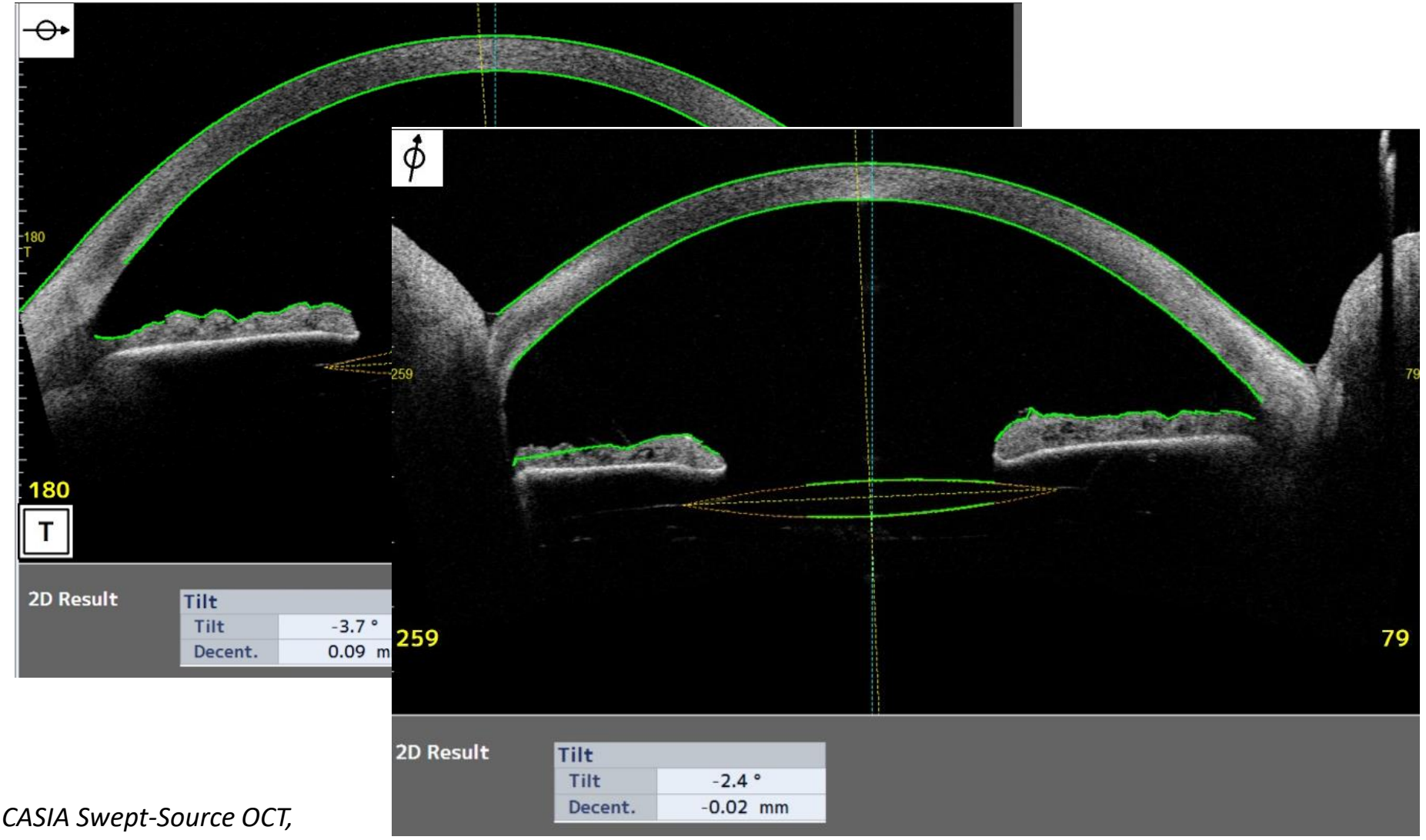
ANATOMICAL OUTCOMES

Characteristics		RayOne population (n=11)
Glistening (%)	<50 microvacuoles/mm2	100%
	50-150 microvacuoles/mm2	0%
	>150 microvacuoles/mm2	0%
Posterior capsule opacification		0
Rotational stability between Day 3 and 1 month visits (Degrees) (SD)		2,14+/-1,46





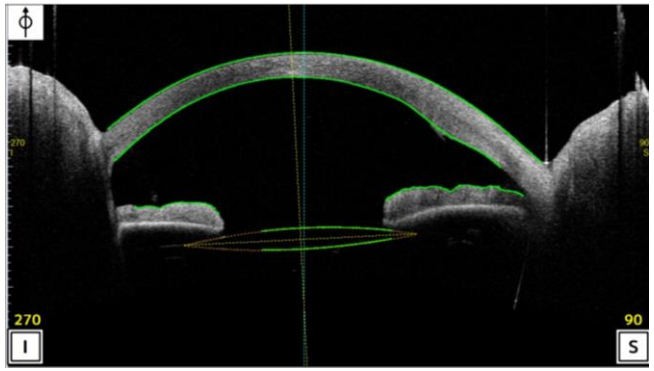
TILT & DECENTRATION



CASIA Swept-Source OCT, Tomey, Japan

TILT & DECENTRATION

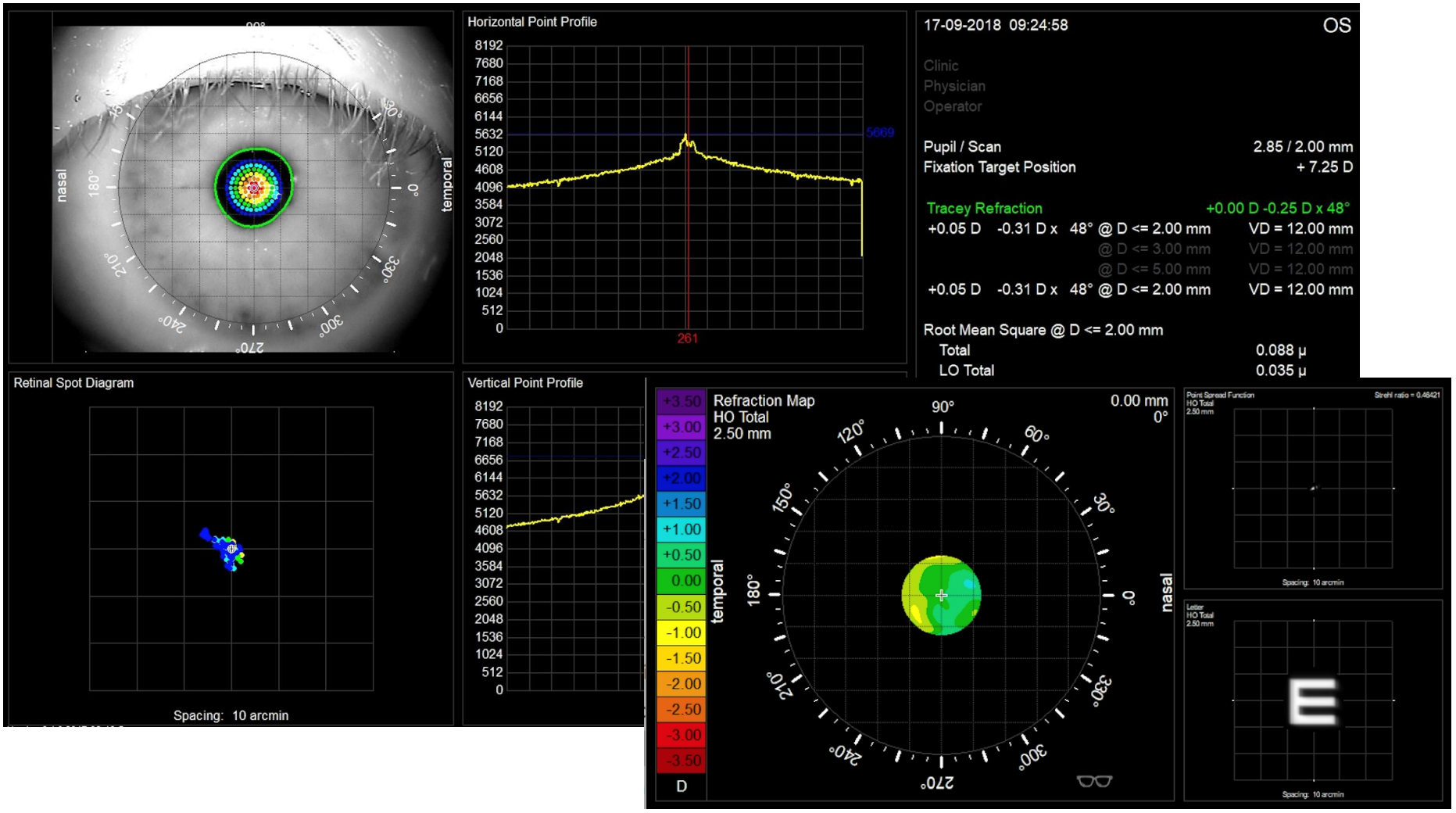
Tilt & Decentration Characteristics	RayOne population (n=11)
Tilt- Horizontal axis (Degrees) (SD)	2,97 +/-0.67
Decentration- Horizontal axis (mm) (SD)	0,08 +/-0.06
Tilt- Vertical axis (Degrees) (SD)	3.23 +/-0,70
Decentration- Vertical axis (mm) (SD)	0,07 +/-0.05



VISUAL & REFRACTIVE OUTCOMES

Visual and refractive outcomes at Month-1 visit	RayOne population (n=11)
Mean postoperative UCVA (LogMAR)	0,04+/-0,07
Mean postoperative BCVA (LogMAR)	0,05+/-0,08
Mean Absolute error of manifest refraction spherical equivalent – Diopter (SD) (Min-Max)	0,22+/-0,25 (0-0,75)

OPTICAL ABERRATION OUTCOMES



iTRACE, Tracey, USA

OPTICAL ABERRATION OUTCOMES

Optical aberration outcomes at Month-1 visit		RayOne population (n=11)
Total Eye High Order Aberrations (Microns) (SD)		0,344+/-0,176
Cornea High Order Aberrations (Microns) (SD)		0,332+/-0,293
Internal High Order Aberrations (Microns) (SD)		0,231+/-0,167
Internal HOAs (Microns) (SD)	**Coma**	0,089+/-0,049
	Spherical	0,025+/-0,048
	Trefoil	0,120+/-0,084

CONCLUSION

- RayOne hydrophobic IOL:
  - Fulfills all current IOL requirements for cataract surgery
  - Preloaded and consistent unfolding & delivery within the capsular bag
  - Excellent visual, refractive and aberrometry measurements outcomes
  - Excellent rotational stability and centration within the bag (Toric & multifocal IOL perspectives)

- Comparative study to be implemented for demonstrating the superiority of optical and biomaterial performances of the RayOne IOL

THANK YOU VERY MUCH FOR YOUR ATTENTION